Carestream

# "510(k) Summary"

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|---|---|
| **510(k) Owner Name:** | Carestream Health, Inc. |
| **510(k) Owner Address:** | 150 Verona Street<br>Rochester, New York 14608 |
| **510(k) Owner Phone:** | 585-627-6528 |
| **510(k) Owner Fax:** | 585-323-7643 |
| **Contact Person & Info:** | Carolyn Wagner<br>Regulatory Affairs Manager, X-Ray Systems<br>carolyn.wagner@carestreamhealth.com<br>585-627-6557 |
| **Date Summary Prepared:** | October 30, 2013 |
| **Device Trade Name:** | Bone Suppression Software |
| **Device Common Name:** | DR digital imager |
| **Classification Name:** | Solid state x-ray imager (flat panel/digital imager) |
| **Device Class:** | Class II |
| **Device Code:** | MQB |
| **Regulation Number:** | 21 CFR 892.1680 |
| **Predicate Devices:** | Kodak Eclipse Image Processing Software<br>Manufactured by Carestream Health, Inc.<br>510(k) No. – K060137 (May 16, 2006)<br><br>Softview, Model 2.01<br>Manufactured by Riverain Medical Group<br>510(k) No. – K092363 (March 18, 2010) |

**Device Description:**

The Bone Suppression Software is a software component for use on diagnostic x-ray systems utilizing digital radiography (DR) or computed radiography (CR) technology. The software option suppresses bone anatomy in order to enhance visualization of chest pathology in a companion image that is delivered in addition to the original diagnostic image.

**Indications for Use / Intended Use:**

The Indications for Use for the device, as described in its labeling, are:
"The software's intended use is to assist diagnosis of chest pathology by minimizing anatomical distractions such as the ribs and clavicle in chest x-ray images."

The intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. The Bone Suppression software component provides a bone suppressed companion image with posterior ribs and clavicle suppressed to aid diagnosis in chest radiographs. We believe that the Bone Suppression Software and the predicate devices have the same intended use.

The Indications for Use for the "Bone Suppression Software" is different than the Kodak Eclipse Image Processing Software predicate device, but these differences do not alter the intended diagnostic use of the software component. The Kodak Eclipse Image Processing Software optimizes radiographic images for diagnosis. The Bone Suppression companion view is generated using an additional image processing step that provides a bone-suppressed image to aid diagnosis in chest radiographs.

The Indications for Use for the "Bone Suppression Software" is worded differently than the Riverain "SoftView, Model 2.1" predicate device, but these differences are appropriately described as descriptive and do not alter the intended diagnostic use of the software component. Both devices provide a bone-suppressed companion view to minimize distractions in chest images. Both devices provide the original "standard of care" image along with the companion image.

Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination.

**Comparison of Technological Characteristics:**

The Bone Suppression Software is an extension of the predicate device, the Kodak Eclipse Image Processing Software. The Bone Suppression Software is an optional software component that allows a companion image to be formed with bone anatomy suppressed in order to enhance visualization of chest pathology. It is available as an integrated optional feature within the predicate device Kodak Eclipse Image Processing Software (DirectView software). The new software device (feature) raises no new issues of safety or effectiveness.

The Bone Suppression Software has the same technological characteristics as the predicate device, the SoftView, Model 2.01. Both devices provide an additional companion image with bone anatomy suppressed in order to enhance visualization of chest pathology. Both devices provide the companion view along with the original

"standard of care" chest radiograph. The Carestream "Bone Suppression Software" device raises no new issues of safety or effectiveness.

**Discussion of Testing**

Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Nonclinical testing was conducted under simulated use conditions. Clinical testing was conducted to evaluate the acceptability of the companion images for assisting diagnosis. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

Carestream Health, Inc.
% Ms. Carolyn Wagner
Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

Re: K133442
Trade/Device Name: Bone Suppression Software
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 28, 2014
Received: February 28, 2014

Dear Ms. Wagner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael O. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K133442

Device Name
Bone Suppression Software

Indications for Use *(Describe)*
The software's intended use is to assist diagnosis of chest pathology by minimizing anatomical distractions such as the ribs and clavicle in chest x-ray images.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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